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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,391	08/21/2003	Martin Gleave	UBC.P-035	9734
57381	7590	04/14/2006	EXAMINER	
Marina Larson & Associates, LLC P.O. BOX 4928 DILLON, CO 80435			BOWMAN, AMY HUDSON	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/646,391		GLEAVE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Amy H. Bowman		1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 2/1/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 11/10/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. Therefore, prosecution has been reopened.

Claims 1-13 are pending in the application. Claims 11-13 are withdrawn as being directed to a non-elected invention.

### ***Response to Arguments--Claim Objections***

Claims 3, 6 and 9 stand objected to for the reasons of record in the office action mailed 4/8/05 and maintained in the office action mailed 9/7/05.

Applicant asserts that the examiner stated that claims 3, 6 and 9 are objected to because the sequences listed therein include sequences in addition to elected SEQ ID NO: 4 and that it is unclear why the examiner refers to claim 3 as an improper Markush group, since it does not contain a Markush group listing of alternatives.

As explained in the office action mailed 9/7/05, the subject matter of claims 3, 6 and 9 that is not drawn to instant SEQ ID NO: 4 and the translation initiation site, is considered withdrawn as being drawn to non-elected subject matter and the claims are objected to because they contain subject matter that is withdrawn. Therefore, claim 3 is objected to for containing subject matter that is not drawn to the translation initiation

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site. The sequences of claims 6 and 9 were restricted because the sequences are not considered proper Markush members.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 recite, "...to reduce the effective amount of clusterin..." It is not understood what the metes and bounds of the term "effective" are. The specification has defined "effective amount of clusterin" on page 3 as referring to the amount of clusterin which is present in a form which is functional to provide anti-apoptotic protection. However, it is unclear what amount is required to be functional to provide anti-apoptotic protection. It is unclear what is required to be an effective amount and what exactly the amount is effective to do.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to a method for treatment of melanoma in a mammalian subject, comprising the step of administering to the subject a therapeutic agent effective to reduce the effective amount of clusterin in the melanoma cells.

At the outset, it is noted that the claimed method does not recite a specific type of therapeutic agent, but rather refers to the administration of any therapeutic agent effective to reduce the effective amount of clusterin in the melanoma cells.

The claim encompasses a method of administering any therapeutic agent effective to reduce the effective amount of clusterin in melanoma cells, including small molecule inhibitors, antibodies, dsRNA duplexes, miRNAs, as well as encompass the administration of any other therapeutic agent that reduces the effective amount of clusterin in melanoma cells. Although the specification discloses antisense and RNAi as means of reducing the amount of clusterin in melanoma cells, the specification does not describe any other therapeutic agent that is effective to reduce the effective amount of clusterin in melanoma cells in a mammalian subject to describe the instantly claimed genus of administering any therapeutic agent that is effective to reduce the effective amount of clusterin in melanoma cells in a mammalian subject. The method utilizing one specific antisense oligo, SEQ ID NO: 4, in an antisense treatment method for various cancers, as exemplified in the 1.132 declaration, does not adequately describe

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the scope of the instantly recited genus which encompasses administering not only any antisense oligonucleotide, but any therapeutic agent to reduce the effective amount of clusterin in melanoma cells.

One of ordinary skill in the art could not make and administer such therapeutic agents to reduce the effective amount of clusterin in melanoma cells without knowledge of the specific types of agents. Given the breadth of therapeutic agents embraced in the instantly claimed genus, one could not envision the member genus of agents.

The scope of the claimed invention is broad and the skilled artisan would not be able to envisage the genus claimed of therapeutic agents effective to reduce the effective amount of clusterin in melanoma cells such that the skilled artisan would recognize that the applicant was in possession of the claimed genus at the time of filing.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman  
Examiner  
Art Unit 1635

  
JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER